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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/114,810 07/13/98 ATALA

A CME-117

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QM12/0222

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EXAMINER

LAHIVE AND COCKFIELD
28 STATE STREET
BOSTON MA 02109

RODRIGUEZ, C	
ART UNIT	PAPER NUMBER

3763

#12

DATE MAILED:

02/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/114,810

Applicant(s)

ATALA ET AL.

Examiner

Rodriquez L Cris

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,19 and 51-53 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

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DETAILED ACTION

Drawings

1. The drawings are objected to because on page 15 line 12, reference numeral "27" is not shown in figure 9; on page 16 line 7, reference numerals "60" and "20c" are not shown in the drawings; Figure 10 does not have a transversal cut line to show what is shown in figure 11.

Correction is required.

Specification

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of 37 CFR 1.71(a)-(c):

(a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

(b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

© In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

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The specification is objected to under 37 CFR 1.71 because the specification, as originally filed, does not provide support the invention as now claimed. The specification does not have support for “phosphodiesterase type 5 inhibitor” as set forth in claims 52 and 53.

Claim Rejections - 35 USC § 112

3. Claims 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth above.
4. Claims 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53, there is no antecedent basis for “the phosphodiesterase type 5 inhibitor”.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

6. Claims 1, 4-6 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ball et al(6,024,717).

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Ball et al discloses an drug delivery ultrasonic device, all figures but mainly figures 5 and 6, comprising an applicator 202 and an oscillatory drive assembly 204 that may comprise floating mass transducer as described in the patent that works as an ultrasound transducer, wherein the oscillating element generates ultrasound energy at a frequency between the range of 10 kHz to 4 MHZ.(col. 9 lines 58-60).

7. Claims 1, 3, 19 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Ogden(5,656,016).

Ogden discloses a therapeutic drug delivery device comprising an applicator 12, an ultrasound transducer, a detector for monitoring feedback signals from the transducer (col 4 lines 17-23), and a control system having a pressure-sensitive switch that turns the ultrasonic generator on and off (col. 3 lines 8-14). The ultrasound transducer has an oscillating element that generates ultrasound energy at a frequency between the range of 20 kHz to 300 MHZ and power of about 0 to 4 watts per centimeter.(col. 3 lines 1-7).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogden and Ball et al.

Ogden and Ball et al discloses the invention substantially as claimed as disclosed supra. These references disclose the use of therapeutics agents being applied transdermally. However, Ogden and Ball et al does not discloses the therapeutic agents as claimed by Applicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ogden and Ball et al by using the therapeutics agents claimed by Applicant in order to transdermally treat a patient for certain medical condition to fulfill Applicants intention.

Response to Arguments

10. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tu et al, Wang et al, Unger et al, and Kost et al all disclose a ultrasonic delivery devices analogous to that as claimed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

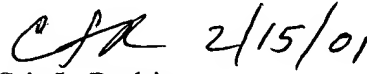
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on Monday-Friday from 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, Richard Seidel can be reached on (703) 308-5115. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

 2/15/01
Cris L. Rodriguez
February 15, 2001

ANH TUAN T. NGUYEN
PRIMARY EXAMINER

2/16/01 A/S.